

Docket No.: MED-0065
(049962.00002)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
J. Daniel Raulerson et al

Application No.: 10/695,178

Confirmation No.: 4287

Filed: October 28, 2003

Art Unit: 3763

For: MULTIPLE CATHETER ASSEMBLY

Examiner: Quynh-Nhu H. Vu

APPEAL BRIEF

MS Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

Appellants hereby request consideration and reversal of the Final Rejection of claims 41-49 as set forth in the Final Office Action dated November 7, 2011 and the Advisory Action dated February 23, 2012.

This Brief is presented in the format required by 37 C.F.R. § 41.37, in order to facilitate review by the Board. In compliance with 37 C.F.R. § 41.37(a)(1), this Brief is being filed within the time allowed for response to the action from which the Appeal was taken or within two months from the date of the Notice of Appeal, whichever is later.

The fees for filing a Brief in support of an Appeal under 37 C.F.R. § 41.20(b)(2) are provided herewith.

I. REAL PARTY IN INTEREST

The real party in interest for this appeal is Medical Components, Inc.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

A. Current Status of Claims

1. Claims canceled: 1-40
2. Claims pending: 41-49
3. Claims allowed: none
4. Claims rejected: 41-49

B. Claims on Appeal

The claims on appeal are claims 41-49.

IV. STATUS OF AMENDMENTS

An Amendment and Response to Final Office Action was filed on February 7, 2012, after the Final Rejection. The February 7, 2012 Amendment amended the specification to address the objections raised in the Final Office Action, but did not amend the claims. The Advisory Action issued on February 23, 2012 did not indicate whether the Amendment was entered or whether the objections were overcome. Applicants respectfully request entry of the February 7, 2012 Amendment and withdrawal of the objections to the specification set forth in the Final Office Action.

V. SUMMARY OF CLAIMED SUBJECT MATTER

As set forth in pending independent claim 41, the presently claimed invention relates to a multiple catheter assembly. With reference to Fig. 1, the specification explains in paragraph [0027] that the multiple catheter assembly 100 includes a first catheter 110 at least partially releasably joined to a second catheter 130. The first catheter 110 includes a first proximal end region 112, and a first distal end region 114 having a first distal tip 116. The second catheter 130 includes a second proximal end region 132, and a second distal end region 134 having a second distal tip 136. The first catheter 110 is preferably an arterial lumen used to draw fluid, such as blood, from the patient, while the second catheter 130 is preferably a venous lumen used to return the fluid to the patient after processing, such as by hemodialysis.

As explained in paragraphs [0039] – [0040], with reference to Fig. 7, splittable bond 180 releasably connects the first catheter 110 to the second catheter 130. The splittable bond 180 includes a distal end 184 and a proximal end 182, either or both of which may be split to allow the proximal end regions 112, 132 and the distal end regions 114, 134 of the first catheter 110 and second catheter 130, respectively, to be manipulated independently of each other. Splitting the proximal end 182 of the splittable bond 180 allows independent movement of the first proximal end region 112 and the second proximal end region 132. Such independent movement allows for longitudinal translation of a hub 150 (not shown in FIG. 7) along a length of the catheter assembly 100.

As explained in paragraph [0036], the hub 150, as shown in FIGS. 1, 5, and 6, is operable between an open position and a closed position and has a distal end 152 and a proximal end 154. The hub 150 is designed to allow both of the catheters 110, 130 in the multiple catheter assembly 100 to enter the distal end 152 of the hub 150 together. A distal channel 155 runs longitudinally through the hub 150 to house the catheters 110, 130. At a predetermined point along the hub 150, the distal channel 155 branches out, from the single distal channel 155, near the distal end 152 of the hub 150, to a first proximal channel 158 and a second proximal channel 159 near the proximal end 154 of the hub 150. Each of the first proximal and second proximal channels 158, 159 houses one or more individual catheters 110, 130 but less than the number of catheters

housed by the distal channel 155. As illustrated in Figs. 1 and 12, the hub 150, and the corresponding inner channels, is of a length such that the proximal ends 111, 131 of the first and second catheters 110, 130, respectively, extend proximally of the hub 150 through openings at the proximal end of the hub 150.

As explained in paragraphs [0050] – [0057], with reference to Figs. 10-12, the catheter assembly 100 is preferably initially inserted into the patient without the hub 150. After insertion and tunneling are complete, the proximal end of the catheter assembly 100 extends from the tunnel 24. It is desirable to secure the hub 150 proximate to the tunnel 24. Since patient anatomy and the procedure utilized may vary, it may be necessary to split the proximal end 182 of the bond 180 to move the hub 150 closer to the tunnel 24 with the bond proximal end 182 within the hub distal channel 155 and proximate to the intersection with the first and second channels 158 and 159.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. Whether the Examiner erred in concluding that claims 41, 42 and 44-49 are obvious under 35 U.S.C. 103(a) based on U.S. Patent No. 5,947,953 (Ash et al.) in view of U.S. Patent No. 4,405,313 (Sisley et al.) further in view of either U.S. Patent No. 4,037,599 (Raulerson) or U.S. Appln. Publication No. 2002/0120224 (Zia et al.).
- B. Whether the Examiner erred in concluding that claim 43 is obvious under 35 U.S.C. § 103(a) based on U.S. Patent No. 5,947,953 (Ash et al.) in view of U.S. Patent No. 4,405,313 (Sisley et al.) further in view of either U.S. Patent No. 4,037,599 (Raulerson) or U.S. Appln. Publication No. 2002/0120224 (Zia et al.) and further in view of U.S. Patent No. 5,800,414 (Cazal).

VII. ARGUMENT

- A. The Examiner erred in concluding that claims 41, 42 and 44-49 are obvious under 35 U.S.C. 103(a) based on Ash et al. in view of Sisley et al. further in view of either Raulerson or Zia et al.

“To establish a prima facie case of obviousness, ... the prior art reference (or references when combined) must teach or suggest all the claim limitations.” M.P.E.P. §2143. Additionally, as set forth by the Supreme Court in *KSR Int'l Co. v. Teleflex, Inc.*, No. 04-1350 (U.S. Apr. 30, 2007), it is necessary to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the prior art elements in the manner claimed.

Independent claim 41 recites “[a] multiple catheter assembly, comprising: a first flexible catheter having a first distal end configured for implantation into a patient and a first proximal end configured for attachment to a first medical element; a second flexible catheter having a second distal end configured for implantation into a patient and a second proximal end configured for attachment to a second medical element, the first and second flexible catheters attached to one another via a splittable bond extending from a bond distal end to a bond proximal end, the bond proximal end initially spaced a first initial distance from the first proximal end and a second initial distance from the second proximal end, wherein the distances from the proximal ends of first and second flexible catheters to the bond proximal end may be increased by splitting the splittable bond; and a hub member defining a distal passage configured to receive the attached first and second flexible catheters and first and second proximal passages intersecting the distal passage at an intersection, the first proximal passage configured for passage of the first flexible catheter and having a length less than the first initial distance such that the first flexible catheter extends from a first proximal opening of the hub member, the second proximal passage configured for passage of the second flexible catheter and having a length less than the second initial distance such that the second flexible catheter extends from a second proximal opening of the hub member, wherein the hub member is configured such that the hub member is longitudinally adjustable along the flexible catheters to position the bond proximal end proximate to the hub member intersection.”

As explained in paragraph [0008] of the current application, “the surgeon may desire or require a different length of a subcutaneous tunnel for a different patient. However, the location of the catheter hub may dictate the length and/or location of the subcutaneous tunnel. It would be beneficial to provide a catheter assembly that has an adjustable location for the hub along the catheter assembly to provide the surgeon options for securing the catheter assembly to the patient.” The presently claimed invention allows the location of the hub and the configuration of the flexible catheters to be adjusted to facilitate a desired positioning of the hub.

None of the cited references, alone or in any reasonable combination, teach or suggest splittable flexible catheters with a hub member having a split passage which is longitudinally adjustable along the catheters to position the bond proximal end proximate to the hub member intersection.

The Final Office Action cites to Ash et al. as teaching a hub and to Sisley et al. for the general proposition of catheters extending through a hub. The Final Office Action cites to Raulerson and Zia et al. as teaching tubing apparatus that may be opened and therefore concludes that the combined structure of Ash et al. and Sisley et al. may be adjustable. Applicant respectfully submits that such a combination overlooks the teaching of the prior art away from such a combination.

Ash et al., which was filed after the issuance of Sisley et al., specifically teaches an assembly wherein the hub 24 forms a part of the passage between the catheters and the extension tubes. More specifically, Ash et al. explains at column 12, lines 15-32 that

As discussed above, the cannulating portion 20 of the assembly 10 is preferably joined to the extension tube portion 22 in the hub 24. As shown in FIGS. 1 and 2, the extension tube portion 22 includes a first extension tube 84 having a distal end 86 and a proximal end 88, and a second extension tube 90 having a distal end 92 and a proximal end 94. The proximal ends 88, 94 are shown in FIG. 1, and the distal ends 86, 92 are shown in FIG. 2. **The extension tube distal ends 86, 92 and the respective proximal openings 78, 82 of the catheters 26, 30 are brought into fluid communication with each other via tunnels 116, 118 molded in the hub 24.** The extension tube proximal ends 88, 94 are preferably connected to respective female luer locks 96, 98 in a conventional manner. If desired, the female luer locks 96, 98 may be substituted with any suitable type of quick connect fittings, ferrule connectors, threadable connector, and the like.

(emphasis added). Ash et al. teaches that tunnels molded into the hub provide fluid communication between the catheters and the extension tubes. Raulerson teaches a similar structure wherein hub conduit portions 25 and 27 provide fluid communication between the catheter 14 and the fluid conduits 44 and 46. (See Fig. 2 of Raulerson). For the devices of Ash et al. and Raulerson to function properly, the ends of the catheters must be fixed within the hub.

One skilled in the art would not simply overlook the teachings of Ash et al. and Raulerson, i.e. to fix the catheter ends within the hub and use the hub portions as fluid conduits, and instead pass the catheters completely through the hub 24 as suggested in the Final Office Action. As set forth in M.P.E.P. 2141.02 VI, “[a] prior art reference must be considered in its entirety, i.e. as a whole, including portions that would lead away from the claimed invention.” (citations omitted).

Furthermore, Sisley et al. also teaches away from the claimed invention. As set forth at column 5, lines 31-35, Sisley et al. teaches a splitter 22 which wraps the junction of the tubes 12 and 14 and which eliminates further splitting of the tubes 12 and 14. The splitter 22 is fixed in position and is not intended to be adjustable, but instead is intended to fix the split relationship of the tubes. The Advisory Action acknowledges that “*The device of Ash in view of Sisley will bring the benefit of eliminating splitting of the catheter tubes.*” The Advisory Action acknowledges that the combination teaches away from splitting of the catheter tubes.

Such is consistent with the teach of Sisley et al. which is not concerned with splitting the tubes, but instead teaches the figure-8 configuration to increase flexibility of the dual lumen and to reduce the amount of material used. Sisley et al. explains that the second fill-in portion thereof can extend over substantially the entire remaining length of the catheter. (See column 4, lines 15-39).

Zia et al. and Raulerson are cited for teaching hinged hub assemblies, however, neither of these references teach hub assemblies having a split passage which is longitudinally adjustable along the catheters to position the bond proximal end proximate to the hub member intersection and to have proximal passage lengths less than the lengths of the proximal portions of the flexible catheters such that the flexible catheters extend from respective openings in the hub. The device of Zia et al. is simply a tube holder to prevent kinking and to facilitate transport or

support. A singular tube runs through the housing of Zia et al. and there is no teaching of splitting or adjusting the housing relative to a bonded portion of the catheters. Raulerson teaches a housing in which the catheter tubes terminate and provides fixed locations for the catheter tube ends.

Ash et al. and Raulerson both teach a device wherein the catheter ends must be fixed within a hub which defines portions of the fluid channels and Sisley et al. teaches a device wherein a splitter is wrapped about the junction of the tubes to eliminate further splitting of the tubes. Zia et al. teaches a tubing apparatus for a single tube and does not provide any teaching of an adjustable hub along a splittable catheter. The cited references teach away from the claimed invention and there is no reasonable basis to combine the references as suggested in the Final Office Action.

The remaining references are cited for limited teachings and do not overcome the shortcomings of Ash et al., Sisley et al., Zia et al. and Raulerson. It is respectfully submitted that independent claim 41 is in condition for allowance. Claims 42 and 44-49 each depend from claim 41 and are allowable for at least the reasons set forth above.

- B. The Examiner erred in concluding that claim 43 is obvious under 35 U.S.C. § 103(a) based on Ash et al. in view of Sisley et al. further in view of either Raulerson or Zia et al. and further in view of Casal.

Claim 43 depends from claim 41 and further recites “wherein the splittable bond is formed by adhesive.” As discussed above, Ash et al. in view of Sisley et al. further in view of either Raulerson or Zia et al. do not render independent claim 41 obvious. Casal is cited for the limited teaching of first and second catheters splittably joined to each other by adhesive. Casal does not address use of a hub with the catheters and does not overcome the shortcomings of the other references as discussed above. By virtue of depending from claim 41, claim 43 is not obvious over these references.

It is respectfully submitted that claim 43 is in condition for allowance.

VIII. CONCLUSION

In view of the arguments set forth above, Appellants respectfully submit that all pending claims are patentable over the cited references. The rejection of all of the pending claims of record should therefore be reversed with instructions to issue a Notice of Allowability. Such actions are respectfully requested.

The USPTO is authorized to charge or credit Deposit Account No. 50-1943 for any additional fees, or any underpayment or credit for overpayment in connection herewith.

Dated: May 4, 2012

Respectfully submitted,

By /Glenn M. Massina/

By: Glenn M. Massina

Reg. No. 40,081

Fox Rothschild LLP

10 Sentry Parkway, Suite 200

P.O. Box 3001

Blue Bell, PA 19422-3001

Telephone: 610-397-6519

Facsimile: 610-397-0450

E-Mail: ipdocket@foxrothschild.com

Customer No. 33941

CLAIMS APPENDIX

A copy of the claims involved in the present appeal is provided below.

41. A multiple catheter assembly, comprising:

a first flexible catheter having a first distal end configured for implantation into a patient and a first proximal end configured for attachment to a first medical element;

a second flexible catheter having a second distal end configured for implantation into a patient and a second proximal end configured for attachment to a second medical element, the first and second flexible catheters attached to one another via a splittable bond extending from a bond distal end to a bond proximal end, the bond proximal end initially spaced a first initial distance from the first proximal end and a second initial distance from the second proximal end, wherein the distances from the proximal ends of first and second flexible catheters to the bond proximal end may be increased by splitting the splittable bond; and

a hub member defining a distal passage configured to receive the attached first and second flexible catheters and first and second proximal passages intersecting the distal passage at an intersection, the first proximal passage configured for passage of the first flexible catheter and having a length less than the first initial distance such that the first flexible catheter extends from a first proximal opening of the hub member, the second proximal passage configured for passage of the second flexible catheter and having a length less than the second initial distance such that the second flexible catheter extends from a second proximal opening of the hub member,

wherein the hub member is configured such that the hub member is longitudinally adjustable along the flexible catheters to position the bond proximal end proximate to the hub member intersection.

42. The multiple catheter assembly of claim 41, wherein the first and second proximal ends each have a circular cross-section and the portions of the first and second flexible catheters initially attached to one another via the splittable bond each have a semicircular cross-section.

43. The multiple catheter assembly of claim 41, wherein the splittable bond is formed by adhesive.

44. The multiple catheter assembly of claim 41, wherein the first flexible catheter has a first distal end region between the bond distal end and the first distal end of the first flexible catheter, the second flexible catheter has a second distal end region between the bond distal end and the second distal end of the second flexible catheter, and the first and second distal end regions are separate from one another.

45. The multiple catheter assembly of claim 44, wherein the first and second distal end regions each define side apertures extending through a respective surface thereof.

46. The multiple catheter assembly of claim 41, wherein the bond distal end is initially spaced a third initial distance from the first distal end and a fourth initial distance from the second distal end, and wherein the third and fourth initial distances are different from one another.

47. The multiple catheter assembly of claim 41, wherein each of the first and second proximal ends includes a respective connection member.

48. The multiple catheter assembly of claim 47, wherein each connection member includes a compression fitting.

49. The multiple catheter assembly of claim 41, wherein the distal passage, or the first and second proximal passages, or the distal passage and the first and second proximal passages are configured to have a friction fit with respect to flexible catheters.

Application No.: 10/695,178

Docket No.: MED-0065 (049962.00002)

EVIDENCE APPENDIX

None

Application No.: 10/695,178

Docket No.: MED-0065 (049962.00002)

RELATED PROCEEDINGS APPENDIX

None